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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,678	11/28/2000	Kan-Hung Lee	TAI-3L6	7845

7590 10/16/2003

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Portland, OR 97204-1378

EXAMINER

SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/724,678

Applicant(s)

LEE ET AL.

Examiner

Jehanne E Souaya

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see Attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1-5 and 21-26.

Claim(s) withdrawn from consideration: 6-20.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ATTACHMENT

1. The proposed amendment filed August 25, 2003 will not be entered because the proposed claim amendments raise new issues under 35 USC 103. Specifically, the proposed claim amendments, the recitation of “comprising” to “consisting of” raises new issues under 35 USC 103(a) for claims 1-5, 21-26 and newly added claims 27 and 28. Further while, the proposed amendment to claim 5, from “comprising” to “consisting” language overcomes the rejections under 35 USC 102, such claim amendments raise new issues under 35 USC 103.
2. With regard to applicant’s traversal of the rejections, the arguments will be addressed as they apply to the pending claims. As such, arguments to pertaining to “discrete portions” or “particular conserved regions” as they apply to “consisting” language will not be addressed. The response traverses the rejection of claims 1-5 and 21-26 under 35 USC 103. The response asserts as set out in the MPEP, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination and that the fact that the claimed invention is within the capabilities of the ordinary artisan is not sufficient to establish prima facie obviousness. These arguments have been thoroughly reviewed but were found unpersuasive. Firstly, the prior art does teach a need for improved methods and reagents for detection. Specifically, Kilpatrick teaches that there is a need for a detection system that identifies and differentiates most or all enterovirus serotypes and that such would improve the speed and accuracy of processing samples and increase the sensitivity of detecting minority populations of enteroviruses in mixed serotype cultures (col. 6, lines 31-35). Secondly, the examiner did not rely only upon the fact that the manipulations required to arrive at the instantly claimed invention were well within the skill of the ordinary

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artisan to establish the prima facie case of obviousness but to point out that the manipulations could be made. Such an argument was used to show that there was a reasonable expectation of success that manipulations could be made that would be useful in the method. Although the region targeted by Kilpatrick is not the same as that targeted by the presently claimed primers and probes, Kilpatrick teaches that sequence identities for different enteroviruses are more than 50% over the whole genome, and that within species, the sequence identity is over 75% over the whole genome (col. 2, lines 35-39). Therefore, the ordinary artisan would have also had a reasonable expectation of success that other regions in the enteroviral genome existed that were conserved. Furthermore, with regard to the assertion that an improper prima facie obviousness has been applied, these arguments have been thoroughly reviewed but were found unpersuasive. In the previous office action, the examiner addressed both issues. Specifically, the previous office action stated: "In the recent court decision *In re Duel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. However, regarding structural and functional homologues, the court stated

"Normally, a prima facie case of obviousness is based upon structural similarity, ie, an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologues because homologues often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try and obtain compounds with improved properties."

The claimed oligonucleotide probes and primers represent structural homologues with similar properties to the sequences disclosed by Kilpatrick. The sequences are from conserved portions of the enteroviral genome and are used in methods of detecting and differentiating enteroviruses

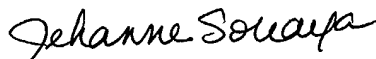
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species from each other. A biochemist of ordinary skill in the art would be motivated to and attempt to obtain alternate compounds with improved properties. Such analysis is considered well within the skill of the ordinary artisan as the nucleic acid sequences of the enteroviral genome, including the sequences targeted by the instantly claimed probes and primers, were sequenced and readily available at the time the invention was made. Further, the teachings of Kilpatrick provide the ordinary artisan with a reasonable expectation of success that structural and functional homologues of the primers and probes developed by Kilpatrick could be made.” For these reasons and the reasons made of record in previous office actions, the rejection is maintained.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Jehanne Souaya
Primary Examiner
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October 9, 2003